SHANGHAI LANFAN CO., LTD
202 Huaxia Bank Tower 256 Pudong Road South, Shanghai 200120 China
Tel: +86-21-68865927 Fax: +86-21-68866351

ATTACHMENT IV: 510 (k) EXECUTIVE SUMMARY. K072488

POWDER-FREE VINYL EXAMINATION GLOVE

OCT 19 2007

Submitter's Name	Shanghai Lanfan Co., Ltd
Submitter's address	2002 Huaxia Bank Tower 256 Pudong Road South, Shanghai 200120 China
Submitter's Telephone Number	+86-21-68865927
Submitter's Fax Number	+86-21-68866351
Name of Contact Person	Kaifeng Bei
Date of Preparation	August 1, 2007
Name of Device	Powder-free Vinyl Exam Gloves,
Trade Name	Lanfan Brand and other customers Private labeling
Common Name	Patient Examination Gloves, Vinyl
Classification Name	Patient Examination Gloves, Vinyl Powder-free (per proposed 21 CFR 880.6250)
Device Classification	Class I
Regulation Number	21 CFR 880.6250
Panel	General Hospital (80)
Product Code	LYZ
Device Description	The Powder-free vinyl exam glove is a disposable Class 1 medical device made from PVC material and is intended to be worn on the hands of health care personnel for medical purpose to provide a barrier against potentially infectious materials and other contaminants.
Legally Marketed Device To Which Equivalency is Being Claimed	Powder-free vinyl Exam gloves are described in the 510 (k) notification are substantially equivalent to the Class I patient examination gloves, Vinyl, 80LYZ Powder free by PU coating, that meets the current ASTM D5250-06 "Standard Specification

Predicate Device Summary of Technological Characteristics Compared to the Predicate Device Performance testing report	for Polyvinyl Examination Gloves for Medical Application" A) K070149 POWDER-FREE VINYL PATIENT EXAMINATION GLOVES, MANUFACTURED BY: WUXI SHENZHOU PLASTIC PRODUCTS CO., LTD. B) K052985 POWDER FREE VINYL EXAMINATION GLOVE MANUFACTURED BY: TG MEDICAL (CHINA) INCORPORATION There are no different technological characteristics. Gloves are made from PVC material.
Intended Use of the Device	Powder-free Vinyl Examination Glove is intended for single use for medical purposes and are worn on the hand of heath care and similar personnel to prevent contamination between the health care personnel and the patients.
Brief Discussion of Non clinical Tests	Testing is performed as per ASTM D5250-06 and 21 CFR 800.20, gloves meet all the current Specifications listed under the ASTM D5250-06 Standard Specification for Vinyl Examination Gloves. Primary Skin Irritation testing in the rabbit and delayed contact Sensitization testing in the guinea pig indicate no irritation or sensitization.
Brief Discussion of Clinical Tests	No new clinical tests were conducted under this 510 (k)
Conclusions Drawn for the Non clinical and Clinical Tests	Non clinical Laboratory and animal data indicate that the powder free vinyl glove meet all performance and biocompatibility requirements.
Other Information Deemed Necessary by FDA	Non Applicable

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bei Kaifeng
Operation Manager
Shanghai Lanfan Company, Limited
2002 Huaxia Bank Tower
256 Pudong Road South
Shanghai 200120
CHINA

OCT 19 2007

Re: K072488
Trade/Device Name: Powder-Free Vinyl Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: August 28, 2007
Received: September 6, 2007

Dear Bei Kaifeng:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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ATTACHMENT I : INDICATION FOR USE

Applicant:

Shanghai Lanfan Co., Ltd

2002 Huaxia Bank Tower 256 Pudong Road South

Shanghai, 200120 China

510 (K) NUMBER (IF KNOWN): K072488

INDICATIONS FOR USE:

A Powder-free Vinyl Patient Examination Glove is disposable device made of PVC material that coated with PU coating to facilitate donning and is intended to be worn on the hand or finger(s) for medical purposes to provide a barrier against potentially infectious materials and other contaminants.

Bei Kaifeng (Operation Manager)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE, IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ (Division Sign-Off) Over-The-Counter-Use X

(Per 21 CFR 801.109) Division of Anesthesiology, General Hospital
Infection Control, Dental Devices (Optional Format 1-2-96)

510(k) Number: K072488